

WAC 246-895-050 Equipment. Equipment used for the manufacture, processing, packing, labeling, holding, testing, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose. The equipment shall:

(1) Be so constructed that all surfaces that come into contact with a drug component, in-process material, or drug product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(2) Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact drug products so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(3) Be constructed and installed to facilitate adjustment, disassembly cleaning and maintenance to assure the reliability of control procedures, uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.

(4) Be of suitable type, size and accuracy for any testing, measuring, mixing, weighing, or other processing or storage operations.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-895-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), § 360-46-050, filed 10/10/88; Order 133, § 360-46-050, filed 8/4/77.]